APPENDIX 3.8.8.

GUIDELINES ON SURVEILLANCE FOR CLASSICAL SWINE FEVER

Article 3.8.8.1.

Introduction

This Appendix defines the principles and provides a guide on surveillance for classical swine fever (CSF) in accordance with Appendix 3.8.1., applicable to countries seeking recognition of freedom from CSF. This may be for the entire country or a *zone* within the country. Guidance for countries seeking reestablishment of freedom from CSF for the whole country or a *zone,* following an *outbreak,* as well as guidelines for demonstrating the maintenance of CSF free status are also provided. This Appendix complements Chapter 2.6.7.

The impact and epidemiology of CSF differ widely in different regions of the world, and it is, therefore, impossible to provide specific guidelines for all situations. It is axiomatic that the surveillance strategies employed for demonstrating freedom from CSF at an acceptable level of confidence will need to be adapted to the local situation. For example, the approach must be tailored in order to prove freedom from CSF for a country or *zone* where wild pigs provide a potential reservoir of infection, or where CSF is present in adjacent countries. The method must examine the epidemiology of CSF in the region concerned and adapt to the specific risk factors encountered. This should include provision of scientifically based supporting data. There is, therefore, latitude available to Member Countries to provide a well-reasoned argument to prove that absence of classical swine fever virus (CSFV) infection is assured at an acceptable level of confidence.

Surveillance for CSF should be in the form of a continuing programme designed to establish that the whole country or a *zone* within the country is free from CSFV infection. Consideration should be given to the specific characteristics of CSF epidemiology which include: the role of swill feeding and the impact of different production systems on disease spread, the role of semen in transmission of the virus, the lack of pathognomonic gross lesions and clinical signs, the frequency of clinically inapparent infections, the occurrence of persistent and chronic infections, and the genotypic, antigenic, and virulence variability exhibited by different strains of CSFV. Serological cross-reactivity with other pestiviruses has to be taken into consideration when interpreting data from serological surveys. A common route by which ruminant pestiviruses can infect pigs is the use of vaccines contaminated with bovine viral diarrhoea virus (BVDV).

For the purposes of this Appendix, virus infection means presence of CSFV as demonstrated directly by virus isolation, the detection of virus antigen or virus nucleic acid, or indirectly by seroconversion which is not the result of vaccination.

Article 3.8.8.2.

General conditions and methods

1. A surveillance system in accordance with Appendix 3.8.1. should be under the responsibility of the *Veterinary Administration.* A procedure should be in place for the rapid collection and transport of samples to an accredited laboratory as described in the *Terrestrial Manual.*

2. The CSF surveillance programme should:

   a) include an early warning system throughout the production, marketing and processing chain for reporting suspicious cases. Farmers and workers, who have day-to-day contact with livestock, as well as diagnosticians, should report promptly any suspicion of CSF to the *Veterinary Authority.* They should be supported directly or indirectly (e.g. through private veterinarians or *veterinary para-professionals)* by government information programmes and the *Veterinary Administration.* Since many strains of CSFV do not induce pathognomonic gross lesions or clinical signs, cases in which CSF cannot be ruled out should be immediately investigated employing clinical, pathological, and laboratory diagnosis. This requires that sampling kits and other equipment are available to those responsible for surveillance. Personnel responsible for surveillance should be able to call for assistance from a team with expertise in CSF diagnosis, epidemiological evaluation, and control;

   b) implement, when relevant, regular and frequent clinical inspections and serological testing of high-risk groups of animals (for example, where swill feeding is practised), or those adjacent to a CSF infected country or zone (for example, bordering areas where infected wild pigs are present).

   An effective surveillance system will periodically identify suspicious cases that require follow-up and investigation to confirm or exclude that the cause of the condition is CSFV. The rate at which such suspicious cases are likely to occur will differ between epidemiological situations and cannot, therefore, be reliably predicted. Recognitions for freedom from CSFV infection should, as a consequence, provide details of the occurrence of suspicious cases and how they were investigated and dealt with. This should include the results of laboratory testing and the control measures to which the animals concerned were subjected during the investigation (quarantine, movement stand-still orders, etc.).

Article 3.8.8.3.

Surveillance strategies

1. Introduction

The target population for surveillance aimed at identifying *disease* and *infection* should include domestic and wild pig populations within the country or zone to be recognised as free from CSFV infection. Such surveillance may involve opportunistic testing of samples submitted for other purposes, but a more efficient and effective strategy is one which includes targeted surveillance.

Depending on the local epidemiological situation, targeted surveillance could be considered as more effective than a randomized surveillance strategy. Surveillance is targeted to the pig population which presents the highest risk of infection (for example, swill fed farms, pigs reared outdoors or farms in proximity to infected wild pigs). Each country will need to identify its individual risk factors. These may include: temporal and spatial distribution of past *outbreaks,* pig movements and demographics, etc.

For reasons of cost, the longevity of antibody levels, as well as the existence of clinically inapparent infections and difficulties associated with differential diagnosis of other diseases, serology is often the most effective and efficient surveillance methodology. In some circumstances, which will be discussed later, clinical and virological surveillance may also have value.

The country should justify the surveillance strategy chosen as adequate to detect the presence of CSFV infection in accordance with Appendix 3.8.1. and the epidemiological situation. Cumulative survey results in combination with the results of passive surveillance, over time, will increase the level of confidence in the surveillance strategy. If a Member Country wishes to apply for recognition by other Member Countries of a specific *zone* within the country as being free from CSFV infection, the design of the surveillance strategy and the basis for any sampling process would need to be aimed at the population within the *zone.*

For random surveys, the design of the sampling strategy will need to incorporate epidemiologically appropriate design prevalence. The sample size selected for testing will need to be large enough to detect infection if it were to occur at a predetermined minimum rate. The sample size and expected disease prevalence determine the level of confidence in the results of the survey. The country must justify the choice of design prevalence and confidence level based on the objectives of surveillance and the epidemiological situation, in accordance with Appendix 3.8.1. Selection of the design prevalence in particular clearly needs to be based on the prevailing or historical epidemiological situation.

Irrespective of the survey design selected, the sensitivity and specificity of the diagnostic tests employed are key factors in the design, sample size determination and interpretation of the results obtained. Ideally, the sensitivity and specificity of the tests used should be

validated for the vaccination/infection history and production class of animals in the target population.

Irrespective of the testing system employed, the surveillance system design should anticipate the occurrence of false positive reactions. This is especially true of the serological diagnosis of CSF because of the recognized cross-reactivity with ruminant pestiviruses. There needs to be an effective procedure for following up positives to ultimately determine with a high level of confidence, whether or not they are indicative of CSFV infection. This should involve confirmatory and differential tests for pestiviruses, as well as further investigations concerning the original sampling unit as well as animals which may be epidemiologically linked.

2. Clinical and virological surveillance

Beyond their role in targeted surveillance, clinical and virological surveillance for CSF has two aims: a) to shorten the period between introduction of CSF virus into a disease free country or *zone* and its detection, and b) to confirm that no unnoticed *outbreaks* have occurred.

One element of clinical surveillance involves the detection of clinical signs of CSF by close physical examination of susceptible animals. The spectrum of disease signs and gross pathology seen in CSF infections, along with the plethora of other agents that can mimic CSF, renders the value of clinical examination alone somewhat inefficient as a surveillance tool. Nevertheless, clinical presentation should not be ignored as a tool for early detection; in particular, any cases where clinical signs or lesions consistent with CSF are accompanied by high morbidity and/or mortality should be investigated without delay. In CSFV infections involving low virulence strains, high mortality may only be seen in young animals.

In the past, clinical identification of cases was the cornerstone of early detection of CSF. However, emergence of low virulence strains of CSF, as well as new diseases - in particular post-weaning multisystemic wasting syndrome and porcine dermatitis and nephropathy syndrome have made such reliance less effective, and, in countries where such diseases are common, can add significant risk of masking the presence of CSF. In *zones* or countries where such diseases exist, careful clinical and virological surveillance of such cases should be applied.

Clinical signs and pathology of CSF infection will also vary considerably, depending on the strain of virus as well as host factors, such as age, nutrition and health status. These factors, along with the compounding effects of concurrent infections and disease caused by ruminant pestiviruses, dictate the need for laboratory testing in order to clarify the

status of CSF suspects detected by clinical monitoring. The difficulties in detecting chronic disease manifested by non-specific clinical signs and delayed seroconversion and seronegativity, in persistently infected piglets, both of which may be clinically normal, makes virological investigation essential. As part of a herd investigation, such animals are likely to be in a minority and would not confound a diagnosis based on serology. Individually or as part of recently mixed batches, such animals may, however, escape detection by this method. A holistic approach to investigation, taking note of herd history, pig, personnel and vehicle movements and disease status in neighbouring *zones* or countries, can also assist in targeting surveillance in order to increase efficiency and enhance the likelihood of early detection.

The labour-intensive nature of clinical, pathological and virological investigations, along with the smaller 'window of opportunity' inherent in virus, rather than antibody detection, has, in the past, resulted in greater emphasis being placed on mass serological screening as the best method for surveillance. However, surveillance based on clinical and pathological inspection and virological testing should not be underrated. If targeted at high risk groups in particular, it provides an opportunity for early detection that can considerably reduce the subsequent spread of disease. Herds predominated by adult animals, such as nucleus herds and artificial insemination studs, are particularly useful groups to monitor, since infection by low virulence viruses in such groups may be clinically inapparent, yet the degree of spread may be high.

Clinical and virological monitoring may also provide a high level of confidence of rapid detection of disease if a sufficiently large number of clinically susceptible animals is examined. In particular, molecular detection methods are increasingly able to offer the possibility of such large-scale screening for the presence of virus, at reasonable cost.

Wild pigs and, in particular, those with a wholly free-living existence, rarely present the opportunity for clinical observation, but should form part of any surveillance scheme and should, ideally, be monitored for virus as well as antibody.

Vaccine design and diagnostic methodologies, and in particular methods of virus detection, are increasingly reliant on up-to-date knowledge of the molecular, antigenic and other biological characteristics of viruses currently circulating and causing disease. Furthermore, epidemiological understanding of the pathways of spread of CSFV can be greatly enhanced by molecular analyses of viruses in endemic areas and those involved in *outbreaks* in disease free areas. It is therefore essential that CSFV isolates are sent regularly to the regional OIE Reference Laboratory for genetic and antigenic characterisation.

3. Serological surveillance

Serological surveillance aims at detecting antibodies against CSFV. Positive CSFV antibody test results can have five possible causes:

a) natural infection with CSFV;

b) legal or illegal vaccination against CSF;

c) maternal antibodies derived from an immune sow (maternal antibodies) are usually found only up to 4.5 months of age, but, in some individuals, maternal antibodies can be detected for
considerably longer periods;

d) cross-reactions with other pestiviruses;

e) non-specific reactors.

The infection of pigs with other pestiviruses may complicate a surveillance strategy based on serology. Antibodies to bovine viral diarrhoea virus (BVDV) and Border disease virus (BDV) can give positive results in serological tests for CSF, due to common antigens. Such samples will require differential tests to confirm their identity. Although persistently infected immunotolerant pigs are themselves seronegative, they continuously shed virus, so the prevalence of antibodies at the herd level will be high. Chronically infected pigs may have undetectable or fluctuating antibody levels.

It may be possible to use sera collected for other survey purposes for CSF surveillance. However, the principles of survey design described in this Appendix and the requirement for statistical validity should not be compromised.

The discovery of clustering of seropositive reactions should be foreseen. It may reflect any of a series of events, including but not limited to the demographics of the population sampled, vaccinal exposure or the presence of infection by field strains or other pestiviruses. Because clustering may signal field strain infection, the investigation of all instances must be incorporated in the survey design. Clustering of positive animals is always epidemiologically significant and therefore should be investigated.

In countries or *zones* that are moving towards freedom, serosurveillance can provide valuable information on the disease status and efficacy of any control programme. Targeted serosurveillance of young stock will indicate whether newly circulating virus is present, although the presence of maternal antibody will also need to be considered. If conventional attenuated vaccine is currently being used or has been used in the recent past, serology aimed at detecting the presence of field virus will likewise need to be targeted at unvaccinated animals and after the disappearance of maternal antibody. General usage in such situations may also be used to assess levels of vaccine coverage.

Vaccines also exist which, when used in conjunction with dedicated serological tests, may allow discrimination between vaccinal antibody and that induced by field infection. Such tools, described in the *Terrestrial Manual,* will need to be fully validated. They do not

confer the same degree of protection as that provided by conventional vaccines, particularly with respect to preventing transplacental infections. Furthermore, serosurveillance using such differentiation requires cautious interpretation on a herd basis.

The results of random or targeted serological surveys are important in providing reliable evidence that no CSFV infection is present in a country or *zone*. It is therefore essential that the survey be thoroughly documented.

Article 3.8.8.4.

Country or zone historically free of CSF ~~in domestic and wild pigs~~

~~1. Historically free status~~

The free status should be reviewed whenever evidence emerges to indicate that changes which may alter the underlying assumption of continuing historical freedom, has occurred. Such changes include but are not limited to:

a) an emergence or an increase in the prevalence of CSF in countries or *zones* from which live pigs or products are imported;

b) an increase in the volume of imports or a change in their country or *zone* of origin;

c) an increase in the prevalence of CSF in the domestic or wild pigs of adjacent countries or *zones;*

d) an increased entry from, or exposure to, wild pig populations of adjacent countries or *zones.*

~~2. Free status as a result of an eradication programme~~

~~In addition to the general conditions described in Chapter 2.6.7., a Member Country seeking recognition of CSF freedom for the country or a *zone*, whether or not vaccination had been practised, should provide evidence for the existence of an effective surveillance programme. The strategy and design of the surveillance programme will depend on the prevailing epidemiological circumstances and will be planned and implemented according to the general conditions and methods described in this Appendix, to demonstrate the absence of CSFV infection in domestic and wild pig populations. This requires the support of a national or other laboratory able to undertake identification of CSFV infection through virus detection and serological tests described in the *Terrestrial Manual*.~~

Article 3.8.8.5

~~Countries, zones or compartments applying for freedom from CSF where vaccination is practised~~

1. Country or zone free of CSF

In addition to the general conditions described in Chapter 2.6.7., a Member Country seeking recognition of CSF freedom for the country or a *zone*, whether or not vaccination had been practised, should provide evidence for the existence of an effective surveillance programme. The strategy and design of the surveillance programme will depend on the prevailing epidemiological circumstances in and around the country or *zone* and will be planned and implemented according to the general conditions and methods described in this Appendix, to demonstrate the absence of CSFV infection in domestic and wild pig populations. This requires the support of a national or other laboratory able to undertake identification of CSFV infection through virus detection and serological tests described in the *Terrestrial Manual*.

2. Compartment free of CSF

The objective of surveillance ~~in this instance is to demonstrate that the two subpopulations are effectively separated by measures that ensure the biosecurity of domestic pigs.~~ is to demonstrate the absence of CSFV infection in the *compartment*. The provisions of Chapter 1.3.5. should be followed. The effective separation of the two subpopulations should be demonstrated. To this end, a biosecurity ~~programme which~~ plan that includes but is not limited to the following provisions should be implemented:

~~a) a programme for the management of CSF in wild pigs;~~

~~b) delineation of CSF wild pig control areas around every CSF case reported in wild pigs;~~

~~c) assessment of the presence and mitigative role of natural boundaries;~~

~~d) documentation of the ecology of the wild pig population;~~

~~e) proper containment of domestic pigs;~~

a) proper containment of domestic pigs;

~~f~~b) control of movement of vehicles with cleaning and disinfection as appropriate;

~~g~~c) control of personnel entering into the *establishments* and awareness of risk of fomite spread;

~~h~~d) prohibition of introduction to the *establishments* of ~~hunted~~ wild caught animals and their products;

~~i~~e) ~~registry~~ record of animal movements into and out of *establishments*;

~~j~~f) information and training programmes for farmers, ~~hunters,~~ processors, veterinarians, etc.

~~3.~~ The biosecurity ~~programme~~ plan implemented ~~would~~ also requires internal and external monitoring by the *Veterinary Authorities.* ~~These elements~~ This monitoring should include ~~but are not limited to~~:

a) periodic clinical and serological monitoring of herds in the country or *zone*, and adjacent wild pig populations following these guidelines;

b) herd registration;

c) official accreditation of biosecurity ~~programme~~ plan;

d) periodic monitoring and review.

~~4.~~ Monitoring the CSF status of wild and domestic pig populations outside the compartment will be of value in assessing the degree of risk they pose to the CSF free ~~domestic population~~ compartment. The design of a monitoring system ~~for wild pig~~ is dependent on several factors such as the size and distribution of the population, the organisation of the *Veterinary Services* and resources available. The occurrence of CSF in wild and domestic pigs may vary considerably among countries. Surveillance design should be epidemiologically based, and the Member Country ~~must~~ should justify its choice of design prevalence and level of confidence based on Appendix 3.8.1.

~~5.~~ The geographic distribution and approximate size of wild pig populations need to be assessed as a prerequisite for designing a monitoring system. Sources of information may include wildlife conservation organisations, hunter associations and other available sources. The objective of a surveillance programme when the disease is already known to exist should be to determine the geographic distribution and the extent of the infection.

Article 3.8.8.6.

Recovery of free status

1. Countries or zones seeking re-establishment of freedom from CSF following an outbreak

In addition to the general conditions described in Chapter 2.6.7., a country seeking reestablishment of country or *zone* freedom from CSF should show evidence of an active surveillance programme ~~for CSF as well as~~ to demonstrate absence of CSFV infection.

Populations under this surveillance programme should include~~, but not be limited to~~:

a) *establishments* in the ~~area~~ proximity of the *outbreak;*

b) *establishments* epidemiologically linked to the *outbreak;*

c) animals used to re-populate affected *establishments* and any *establishments* where contiguous
culling is carried out;

d) wild pig populations in the area of the *outbreak*.

In all circumstances, a Member Country seeking reestablishment of country or *zone* freedom from CSF with vaccination or without vaccination should report the results of an active and passive surveillance programme in which the pig population undergoes regular clinical, pathological, virological, and/or serological examination, planned and implemented according to the general conditions and methods described in these guidelines. The surveillance should be based on a statistically representative sample of the populations at risk.

~~2. Country or zone free of~~ Surveillance for CSF in wild pigs

While the same principles apply, surveillance in wild pigs presents challenges beyond those encountered in domestic populations in each of the following areas:

a) determination of the distribution, size and movement patterns associated with the wild pig population;

b) assessment of the possible presence of CSF within the population;

~~c) determination of the practicability of establishing *zone*~~.

~~The design of a monitoring system for wild pigs is dependent on several factors such as the organisation of the *Veterinary Services* and resources available. The geographic distribution and approximate size of wild pig populations need to be assessed as a prerequisite for designing a monitoring system. Sources of information may include wildlife conservation organisations, hunter associations and other available sources. The objective of a surveillance programme is to determine the geographic distribution and estimation of target population.~~

Estimates of wild pig populations can be made using advanced methods (radio tracking, linear transect method, capture/recapture) or traditional methods based on the number of animals that can be hunted to allow for natural restocking (hunting bags).

For implementation of the monitoring programme, it will be necessary to define the limits of the territory over which wild pigs range in order to delineate the epidemiological units within the monitoring programme. It is often difficult to define *epidemiological units* for wild animals. The most practical approach is based on natural and artificial barriers.

The monitoring programme should also include animals found dead, road kills, animals showing abnormal behaviour or exhibiting gross lesions during dressing.

There may be situations where a more targeted surveillance programme can provide additional assurance. The criteria to define high risk areas for targeted surveillance ~~can be~~ include:

a) areas with past history of CSF;

b) sub-regions with high wild pig density;

c) border regions with CSF affected countries or *zones;*

d) ~~areas of~~ ~~contact~~ interface between wild and domestic pig ~~sub~~ populations;

e) picnic and camping areas;

f) ~~around~~ farms with free-ranging pigs;

g) garbage dumps

h) ~~special~~ other risk areas determined by ~~local~~ the *Veterinary Authorit~~ies~~y~~;~~.

~~g) garbage dumps.~~

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